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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,390	09/09/2002	Jan Dirk van der Klis	5091US	7882

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PO Box 2550  
Salt Lake City, UT 84110

EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/018,390

Applicant(s)

KLIS ET AL.

Examiner

Patricia A Patten

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13-16, 18 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) 27-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-16, 18 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-11, 13-16, 18 and 22-30 are pending in the application.

### ***Election/Restrictions***

Newly submitted claims 27-30 (i.e., Group II) are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 27-30 are drawn to a method for preparing animal feed which comprises fractionating a plant to select for a compound such as isoflavones or lignans for example. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process can be used to create a fraction enriched with lignans which are not phytoestrogens. Further, the products as found in Group I may be made by a materially different process such as de-fatting soybean meal.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-30 are hereby withdrawn from

Art Unit: 1654

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-11, 13-16, 18 and 22-26 were examined on the merits.

It is noted that the changes to the description of the drawings as well as the priority data is accepted and both were entered into the Specification.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

### ***Specification***

The disclosure is objected to because of the following informalities:

Table 2 recites 'Fullfal soybeans'. This is considered a minor spelling error because 'Fullfal' should properly read 'Fullfat'.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-6, 10-11 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inducing calcitriol synthesis and/or increasing phytate degradation capacity of pigs or poultry with soybean meal (fatted or defatted), does not reasonably provide enablement for performing the method with phytoestrogens only. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in

Art Unit: 1654

determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

In the Instant case, it has been discovered that these claims are not enabled for their entire scope. While Applicants have clearly shown that administration of soybean meal, fatted or defatted will raise the level of endogenous calcitriol as well as phytate degradation, Applicants have not convincingly demonstrated that the active ingredient in the soybean is phytoestrogens. There is no evidence in the specification which indicates that phytoestrogens alone will actually lead to increased calcitriol or phytate degradation in poultry. The state of the prior art is unpredictable, because it has not indicated that phytoestrogens alone will lead to increased calcitriol or phytate degradation in poultry.

Soy contains many phytoestrogens and Applicants have not provided any working examples which would clearly show that any of these phytoestrogens increased calcitriol syntheses or phytate degradation. Nor have Applicants provided any scientific reasoning which would give some validation that phytoestrogens alone, when isolated from soy, will perform the Instantly claimed methods. Additionally, there is no indication

which phytoestrogens in soy actually have this effect. For example, Table 1 indicates that peas fed at 51 g/kg of body weight/day which is equivalent to 4 mg/kg of isoflavones per day resulted in a calcitriol blood level of 72 while maize, being fed at an equivalent of 1 mg of isoflavones per kg of body weight produced a calcitriol level of 81. Accordingly, with regard to IP-6 degradation, there is no significant data presented in Table 2 which would indicate that it is actually the isoflavones which are indeed the active ingredient because these results do not appear to show IP-6 degradation in a linear fashion when plotted against mg of isoflavones. Therefore, in order for the skilled artisan to ascertain the effectiveness of the scope of the embodiments recited in these claims, undue experimentation would need to be performed. This experimentation would be undue considering the time consuming and expensive trials that would need to be performed in order to ascertain if in fact it is the phytoestrogens within the soy which are actually the active ingredient manifesting calcitriol syntheses as well as phytate degradation.

### ***Claim Rejections - 35 USC § 102***

Claims 1-4, 7-9, 13-16, 18 and 22-23 and 26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Goff et al. (1995).

Applicants' principal argument resides in the contention that the Examiner did not set forth a *prima facie* case of inherency with regard to the methods disclosed by Goff et al. However, Goff et al. clearly stated that the non-cholecalciferol supplemented corn-soybean meal which was fed to the chickens manifested endogenously produced calcitriol (p.1354 col.2). Therefore, calcitriol was induced in poultry with a composition comprising soymeal which inherently contains phytoestrogens, thereby anticipating the claims. It is reiterated that some claims only state that inducing calcitriol synthesis in animals which is, again, anticipated by Goff et al. because calcitriol synthesis was clearly induced. Other claims state that the method includes feeding the animals a food that induces calcitriol synthesis. Again, Goff et al. fed the chickens a corn-soybean meal which induced calcitriol synthesis, thereby anticipating the claims. Further, the meal must have been in a sufficient amount to induce calcitriol synthesis, because according to their data, calcitriol synthesis was produced thus anticipating the composition claims as well.

Although the Goff et al. reference is silent with regard to decreasing the need for antibiotics in an animal by supplementing the diet with a substance which induces calcitriol synthesis, the method disclosed by Goff et al. anticipates this claim (22) because the only step in the method is to administer the substance, wherein the substance is the corn-soybean meal disclosed by Goff et al.



Applicants argue that increasing immune competence and phytate degradation is an unexpected result (p.10 Arguments). However, Applicants state that it is the increase in calcitriol which leads to these effects. Because Goff et al. taught an increase in calcitriol with corn-soybean meal, increasing immune competence and phytate degradation is considered an inherent property of feeding poultry corn-soybean meal. Applicants contend that these are unexpected results, however, these results appear to be new discoveries of an old method; i.e., an undiscovered mechanism of feeding soy to poultry which was already known in the art.

It is pointed out that claim 1 merely states that the method includes raising calcitriol levels. Again, it is clear from Goff et al. that calcitriol levels were raised in poultry, with the corn-soybean meal as well as the meals supplemented with cholecalciferol thereby clearly anticipating this claim.

It is evident from the prior art that soy-based diet supplementation for poultry was conventional knowledge in the art at the time the invention was made. It is also clear from Goff et al. that a poultry diet supplemented with corn-soymeal has at least some effect on increasing endogenous calcitriol levels thereby anticipating the claimed invention. It is reiterated that there is no evidence set forth in the Instant specification which indicates that phytoestrogens alone manifest the increased calcitriol synthesis in poultry, and subsequently no evidence which would indicate which phytoestrogens would actually be effective.

No Claims are allowed.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0968. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia A Patten  
Examiner  
Art Unit 1654



**PATRICIA PATTEN  
PATENT EXAMINER**

3/01/04

Application/Control Number: 10/018,390

Page 10

Art Unit: 1654